REMARKS

Claims 60, 61, and 63-72 are currently pending. The amendment to claim 64 submitted as part of this response corrects an obvious spelling error in that claim and does not modify its scope nor introduce any new or unsupported subject matter into claim 64.

The Examiner, in an Office Action mailed on May 4, 2006, rejected claims 60, 61, and 63-72 under 35 U.S.C. §103(a) as being unpatentable over Batich et al. Patent Application Publication No. US2002/0177828 ("*Batich*") in view of Schoenfeldt et al. Patent Application Publication No. US2002/0172708 ("*Schoenfeldt*") and further in view of Voorhees et al. Patent Application Publication No. US2004/0235950A1 ("*Voorhees*").

Applicants respectfully traverse the Examiner's §103(a) rejection of claims 60, 61, and 63-72 and request reconsideration and withdrawal of the rejection based on the following remarks.

REJECTION UNDER 35 U.S.C. §103(a) AS BEING UNPATENTABLE OVER BATICH IN VIEW OF SCHOENFELDT AND VOORHEES

The Examiner rejects claims 60, 61, and 63-72 under 35 U.S.C. §103(a) as being unpatentable over Batich in view of Schoenfeldt and further in view of Voorhees. The Examiner asserts that Batich discloses a wound dressing comprised of a substrate covalently bonded to polyionic polymers including vinyl or allyl monomers containing quaternary ammonium groups. The Examiner asserts that the subject matter in claims 67 and 71 are met because Batich discloses the use of diallylmethylammonium salts. The Examiner further asserts that the subject matter of claims 68 and 72 are met because Batich discloses the inclusion of hemostatic agents.

The Examiner admits that Batich does not specifically disclose the use of metalloproteinase inhibitors, such as GM 1489. The Examiner asserts that Schoenfeldt discloses the preparation of non-fibrous material in which an absorbing article contains polyionic polymers with polycationic groups such as amines and/or pharmaceutical medicaments (including metalloproteinase inhibitors such as ilomastat or ethylene diamine tetraacetic acid) and that Voorhees discloses compositions and methods for use against acne-induced inflammation and describes the use of ilomastat and GM 1489.

The Examiner asserts that it would have been obvious to a person having ordinary skill in the art at the time the claimed invention was made to combine Batich with Schoenfeldt and Voorhees because Batich discloses a wound dressing comprising of all the ingredients claimed by Applicants except the use of metalloproteinase inhibitors while Schoenfeldt discloses an article containing polyionic polymers and

metalloproteinase inhibitors and Voorhees discloses acne treatment comprising GM 1489. The Examiner asserts that the motivation to combine the references would be a method for the treatment of skin wounds comprised of contacting skin with a substrate covalently bonded to polyionic polymers ionically associated with metalloproteinase inhibitors such as GM 1489. Applicants respectfully disagree.

Under 35 U.S.C. §103(a),

"a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102. . ., if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains..."

When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:

The claimed invention must be considered as a whole;

The references must be considered as a whole;

The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

Reasonable expectation of success is the standard with which obviousness is determined.

See, e.g., Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

The Examiner organized his assertions in the Office Action by first rejecting claims 67, 68, 71, and 72 under 35 U.S.C. §103(a). Applicants assume that the purpose of Examiner's assertion that Batich discloses a wound dressing comprised of a substrate covalently bonded to polyionic polymers including vinyl or allyl monomers containing quaternary ammonium groups was intended to provide support for his rejection of claims 66 and 70. Applicants respectfully disagree with the Examiner's rejection of claims 66, 67, 68, 70, 71, and 72 and assertion that the claims are "met" by Batich. Use of the term "met" implies that that claims 66, 67, 68, 70, 71, and 72 are anticipated by Batich, which would not constitute a rejection under 35 U.S.C. §103(a). As the Examiner admits, Batich fails to disclose a wound dressing with matrix metalloproteinase inhibitor or an antibiotic, analgesic, anti-inflammatory, or combination thereof ionically associated with a polyionic polymer bonded to a substrate. Because claims 66, 67, 68, 70, 71, and 72 depend from claims 60 and 61, the claims include a wound dressing with either matrix metalloproteinase inhibitors, antibiotics, analgesics, or anti-inflammatories ionically associated with a polyionic polymer. Thus, the subject matter of claims 66, 67, 68, 70, 71, and 72 are not "met" by

Batich because Batich fails to disclose all of the elements of Applicants' invention. In addition, the combination of Batich with Schoenfeldt and Voorhees also fail to support the Examiner's rejection of claims 60, 61, and 63-72.

None of the prior art references cited by the Examiner disclose or suggest ionically associating matrix metalloproteinase inhibitors or an antibiotic, analgesic, anti-inflammatory, or combination thereof with a polyionic polymer covalently bonded to a substrate **to achieve extended release**. There is also no reasonable expectation of success that combining the prior art references would result in a wound dressing with a controlled and sustained release of ionically associated matrix metalloproteinase inhibitors, antibiotics, analgesics, or anti-inflammatories. Therefore, it would not have been obvious to a person having ordinary skill in the art at the time the invention was made to combine Batich, Schoenfeldt, and Voorhees to arrive at Applicants' invention.

Neither Batich, nor Schoenfeldt, nor Voorhees include the element of a matrix metalloproteinase inhibitor, antibiotic, analgesic, or anti-inflammatory ionically associated with a polyionic polymer bonded to a substrate **to achieve extended release**. Thus, the references fail to include all of the elements of Applicants' invention; therefore there is no prima facie case of obviousness.

The Examiner admits that Batich does not specifically disclose the use of metalloproteinase inhibitors and that there is no discussion within Voorhees of combining the metalloproteinase inhibitors with polycationic polymers. Instead, the Examiner assumes that it is obvious that since the Schoenfeldt application describes the use of polycationic polymers with amine groups and metalloproteinase inhibitors, the ionic interaction between the inhibitor and the polyionic polymer would be the same. Applicants respectfully disagree. Examiner misstates the correct standard under 35 U.S.C. §103 to determine obviousness which is whether it would have been obvious to a person having ordinary skill in the art at the time Applicants' invention was made that the ionic interaction between the inhibitor and the polyionic polymer in Schoenfeldt would achieve extended release and is applicable to a polyionic polymer covalently bonded to a substrate.

Although Schoenfeldt discloses the incorporation of certain medicaments in a wound dressing, Schoenfeldt lacks the element of extended release. Schoenfeldt discloses a method for preparing an insoluble porous material by crosslinking anionic and cationic polymers, paragraphs [0018] and [0033]. In the experimental data disclosed in Examples 4, 5, and 6, the physical characteristics of the porous material are described; however, there is no discussion of the wound healing properties of the material or whether it is possible to create a wound dressing with controlled and sustained release of wound healing agents. Schoenfeldt teaches that a pharmaceutical medicament may participate in a crosslinking process, paragraph [0037]; however, if the pharmaceutical medicament is incorporated by crosslinking in an insoluble material, by definition the medicaments within the crosslinked sol-gel would also be

insoluble and therefore unreleasable. Thus, none of the references include the element of extended release.

None of the references teach or suggest Applicants' invention. Schoenfeldt does not suggest that certain wound healing agents can be ionically associated with a polyionic polymer to achieve extended release. Schoenfeldt describes the use of drugs that are polymeric and can participate in the sol-gel reactions leading to the formation of the insoluble dressing material, and in paragraph [0055], he provides a long list of drugs, including small (non-polymer) molecules; however, there is no indication that these are intended or required to have any specific ionic (or other) interaction with the sol-gel matrix, or that they even need to be ionic in nature. Schoenfeldt simply states that that any drug can be added to this material, and gives no discussion of stabilization of the drug or controlled/sustained release or retention. In fact the term "release" is not ever mentioned in the application.

Voorhees also does not disclose or suggest ionically associating matrix metalloproteinase (MMP) inhibitor with a polyionic polymer. Voorhees merely discusses the use of inhibitors of MMPs to treat acne infected skin. There is no discussion of wound dressings or polyionic polymers and no suggestion as to whether the negative charge of a GM1489 molecule and the C-terminal carboxylic acid form of Ilomastat can ionically associate with polyionic polymers in a wound dressing, such as Applicants' invention. Thus, none of the prior art references teach or suggest ionically associating wound healing agents with a polyionic polymer covalently bonded to a substrate to create a wound dressing with a controlled and sustained released of healing agents.

There is no reasonable expectation of success that combining Schoenfeldt and Voorhees with Batich will arrive at Applicants' application. As previously discussed, Schoenfeldt does not disclose a wound dressing with a controlled or sustained release. Schoenfeldt discusses a method of preparing an insoluble material which is a sol-gel that is dried to create a porous wound dressing. The method is therefore inapplicable to a method of covalently bonding a polymer to a substrate. Also in Schoenfeldt, medicaments are added to the sol-gel, so that they can crosslink with the ionic polymers to form an insoluble material and it is unlikely that the agents are releaseable if crosslinked within the material. Voorhees discusses the use of MMP inhibitors to treat acne-infected skin by administering the inhibitors topically or orally, paragraph [10], but does not discuss wound dressings or the controlled release of inhibitors. There is no reasonable expectation of success that the combination of Schoenfeldt, Voorhees, and Batich, which the Examiner admits does not discuss the use of matrix metalloproteinase inhibitors, will result in Applicants' wound dressing comprising a polyionic polymer covalently bonded to a substrate and ionically associated with a wound healing agent to achieve sustained release of said agent.

Applicants disagree with Examiner's assertion that the motivation to combine Schoenfeldt, Voorhees, and Batich would be a method for the treatment of skin

comprised of contacting skin with a substrate covalently bonded to polyionic polymers ionically associated with metalloproteinase inhibitors. The Examiner has effectively used Applicants' invention to combine the references, but they must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention. Applicants' invention is a wound dressing with controlled and sustained release of healing agents that are ionically associated to polyionic polymers covalently bonded to a substrate. None of the prior art references disclose, suggest, or provide a reasonable expectation of success that their combination will produce Applicants' invention; therefore, it would not have been obvious to a person having ordinary skill in the art at the time the invention was made to combine Batich, Schoenfeldt, and Voorhees to create a wound dressing comprising a polyionic polymer bonded to a substrate with ionically associated matrix metalloproteinase inhibitors, antibiotics, analgesics, or anti-inflammatories to achieve extended release of said agents.

CONCLUSION

For the foregoing reasons, Applicants submit that the claims presented herewith are patentable over the prior art of record and respectfully solicits prompt action thereon. If any questions remain, the Examiner is invited to phone the undersigned attorney.

Respectfully submitted: November 6, 2006

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